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**IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF UTAH, CENTRAL DIVISION**

UTAH VAPOR BUSINESS ASSOCIATION,
INC., a Utah nonprofit corporation, *et al.*,

Plaintiffs,

vs.

STATE OF UTAH, *et al.*,

Defendants.

**MOTION FOR TEMPORARY
RESTRAINING ORDER AND
PRELIMINARY INJUNCTION**

Case No. 2-24-CV-00950-HCN

Judge Howard C. Nielson, Jr.

(EXPEDITED HEARING REQUESTED)

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<i>MonaVie, LLC v. Wha Lit Loh</i> , No. 2:11-cv-265, 2011 WL 1233274, at *3 (D. Utah Mar. 31, 2011)	24
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<i>NetChoice, LLC v. Reyes</i> , No. 2:23-CV-00911-RJS-CMR, 2024 WL 4135626, at *17 (D. Utah Sept. 10, 2024)	54, 55
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<i>Planned Parenthood Ass'n of Utah v. Herbert</i> , 828 F.3d 1245, 1263 (10th Cir. 2016)	50
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OTHER AUTHORITIES

Ahmed M Ashour, <i>Use of Vaping as a Smoking Cessation Aid: A Review of Clinical Trials</i> , NATIONAL LIBRARY OF MEDICINE (July 27, 2023)	57
Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 11-31, 123 Stat. 1776 (June 22, 2009)	22
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<i>Menthol in Cigarettes, Tobacco Products; Request for Comments</i> , 78 Fed. Reg. 44, 484, 44,485 (July 24, 2013)	28
Oxford English Dictionary, “Property” (2020).....	27

Premarket Tobacco Product Applications and Recordkeeping Requirements, 84 Fed. Reg. 50, 566, 50, 637 (proposed Sept. 25, 2019)	28
RAI Services Company, Comment Letter on Advance Notice of Proposed Rulemaking Regarding Menthol in Cigarettes, Tobacco Products (Nov. 22, 2013).....	35
RAI Services Company, Comment Letter on Advance Notice of Proposed Rulemaking Regarding Regulations of Flavors in Tobacco Products (July 18, 2018)	35
<i>Regulation of Flavors in Tobacco Products</i> , 83 Fed. Reg. 12,294, 12299 (Mar. 21, 2018).....	28
Samuel P. Newton, <i>Giving Teeth to State Constitutions: Using History to Argue Utah's Constitution Affords Greater Protections to Criminal Defendants</i> , 3 UTAH J. CRIM. L. 40, 42 (2018)	43
Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. 26396 (proposed May 4, 2022).....	28
Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26454 (proposed May 4, 2022).....	28
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Wright & Miller, 11A Fed. Prac. & Proc. Civ. § 2948.2 (3d ed.)	55

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Pursuant to Rules 7 and 65 of the Federal Rules of Civil Procedure, Plaintiffs Utah Vapor Business Association, Inc. (“UVBA”) and The Smoke House, LLC, through counsel, submit their Motion for Temporary Restraining Order and Preliminary Injunction (the “**Motion**”).¹ Due to the exigent circumstances presented by the January 1, 2025 effective date of challenged legislation, Plaintiffs respectfully request expedited consideration of the Motion. An expedited hearing is also requested.

RELIEF REQUESTED AND SUPPORTING GROUNDS

The Electronic Cigarette Amendments, enacted by Senate Bill 61 (“**SB 61**”), will have a devastating impact on small businesses throughout Utah beginning on January 1, 2025, when Retail Tobacco Specialty Businesses (“**RTSB**”) will be prohibited from selling flavored electronic cigarette (“**e-cigarette**” or “**vape**”) products and subjected to unconstitutional searches by local health departments tasked with searching for those items. The Utah Department of Health and Human Services (“**DHHS**”) compounded the issue when it proposed administrative rules that prohibit the sale of any unregistered e-cigarette product. *See* Utah Admin. Code R384-415-4, Utah State Bulletin (Nov. 15, 2024). DHHS published these proposed rules in conjunction with SB 61 and set the same proposed effective date of January 1. *Id.*; *see* Utah Code § 59-14-810(13).

Pursuant to Rule 65 of the Federal Rules of Civil Procedure, Plaintiffs seek a temporary restraining order and preliminary injunction enjoining Defendants from enforcing contested provisions of the Utah Code that were either amended or enacted by SB 61 and from enforcing the

¹ The Motion was originally filed by Plaintiffs concurrently with the Verified Complaint in the State Court action prior to removal to this Court. Pursuant to DUCivR 81-2(c), Plaintiffs hereby refile the Motion, which has been modified to cite to applicable federal law for the standard for granting a temporary restraining order under Fed. R. Civ. P. 65, as opposed to Utah R. Civ. P. 65A.

proposed administrative rules. Specifically, Plaintiffs seek to enjoin the enforcement of statutory provisions and administrative rules that unlawfully prohibit the sale of flavored e-cigarette products, impose a 4% nicotine cap, and authorize local health departments to conduct warrantless onsite searches to seize and embargo such products. Those statutory provisions and rules include:

- Section 10-8-41.6 (removing reference to flavored e-cigarette products from the type of products sold exclusively by RTSBs);
- Section 17-50-333 (same);
- Section 26A-1-131 (permitting local health departments to conduct warrantless searches for unregistered e-cigarette products);
- Section 26B-7-505 (prohibiting the sale of e-cigarette products that are not premarket authorized or pending market authorization by the FDA);
- Section 76-10-101(16)(b) (prohibiting the sale of e-cigarette products containing greater than 4.0% nicotine by weight or with a nicotine concentration of 40 milligrams per milliliter);
- Section 59-14-807 (governing the use of fees and penalties collected through the administration of the registry);
- Section 59-14-810 (creating an e-cigarette product registry and prohibiting the sale of unregistered products);
- Section 76-10-101 (redefining “flavored electronic cigarette product” and exempting from the definition only those products that have the taste or smell of tobacco or menthol);

- Section 76-10-113 (banning the sale of all flavored e-cigarette products and any e-cigarette products that are not premarket authorized or pending authorization, effective January 1, 2025);
- Utah Admin. Code R384-324 (amending administrative rules to align with SB 61 and redefining RTSB to align with restrictions on the sale of flavored e-cigarette products); and
- Utah Admin. Code R384-415 (amending administrative rules to align with SB 61 and prohibiting the sale of any e-cigarette products that are not on the registry created by Utah Code § 59-14-810).

A temporary restraining order and preliminary injunctive are necessary to preserve the *status quo* during the pendency of this litigation. Without such relief, small business owners operating RTSBs throughout the State of Utah will face significant, imminent, and irreparable harm. Beginning January 1, 2025, many, if not all, RTSBs will be forced to cease operations to comply with Utah statutes that are expressly preempted by federal law governing tobacco and e-cigarette products. These retailers will be prohibited from selling products that constitute the bulk of their revenue even though such products are not federally banned. Additionally, on January 1, 2025, local health departments will be authorized to subject RTSBs to warrantless regulatory searches in violation of the owners' state and federal constitutional rights. Plaintiffs urge the Court to enter injunctive relief by December 31, 2024.

RELEVANT BACKGROUND

1. UVBA is a Utah nonprofit corporation and association whose members consist of small business retailers who sell, amongst other items, tobacco products, tobacco paraphernalia,

e-cigarettes and/or nicotine products. UVBA formed in 2018 to represent and advocate on behalf of its members before the Utah State Legislature and executive agencies, such as the DHHS.

2. UVBA has 98 members that consist of 83 RTSBs and 15 manufacturers and distributors.

3. The RTSB members of UVBA generate revenue primarily through the sale of flavored e-cigarette products.

4. DHHS attempted to ban the sale of flavored e-cigarettes in 2019 via an emergency administrative rule (“**DHHS Emergency Flavor Ban**”) by erroneously linking flavored e-cigarettes to an outbreak of a lung disease named E-cigarette or Vaping Product Use-Associated Lung Injury (“**EVALI**”).

5. The Honorable Keith Kelly previously enjoined DHHS’ Emergency Flavor Ban in the case styled *VIP Vapors of Orem, LLC, et al. vs. Joseph K. Miner, et al.*, Case No. 190908334. Judge Kelly found that UVBA met all the requirements for injunctive relief and, in particular, the irreparable harm requirement, “based upon loss of goodwill and likely being put out of business” citing to *Hunsaker v. Kersh* for the proposition that “Loss of business and goodwill may constitute irreparable harm susceptible to injunction.”

6. After the DHHS Emergency Flavor Ban was enjoined, UVBA worked with the Utah Legislature during the 2020 General Session on a compromise.

7. Under the compromise, sales of flavored e-cigarettes would be restricted to RTSBs, where persons under the age of twenty-one are not permitted to enter the business or make any purchases of tobacco products, e-cigarette products, or nicotine products.

8. By restricting flavored e-cigarettes to RTSBs, the Utah Legislature created two distinct types of tobacco retailers.

9. RTSBs became specialty shops with a distinct market advantage as the sole place adult consumers could purchase flavored e-cigarettes.

10. General tobacco retailers such as grocery stores, convenience stores and gas stations like 7-11 and Maverik were limited to selling e-cigarettes with flavors of mint, menthol, and tobacco.

11. While general tobacco retailers cannot derive more than 35% of their total quarterly gross receipts from the sales of tobacco products and e-cigarette products, RTSBs can derive 100% of their total quarterly gross sales from tobacco products, tobacco paraphernalia, e-cigarette products, and nicotine products.

12. When the Utah Legislature moved flavored e-cigarettes into RTSBs, it incentivized RTSB owners to invest significant time, sweat, and capital into obtaining and maintaining the necessary RTSB permits.

13. Opening and operating an RTSB is neither a simple nor inexpensive task. The Utah Legislature has imposed a strict regulatory regime on RTSBs, complete with proximity and other age-based restrictions. For example, RTSBs are not permitted to operate within 600 feet of any other RTSB or any of property used or zoned for agriculture or residential use, and RTSBs are not permitted to operate within 1,000 feet of a “community location.”² Meanwhile, general tobacco retailers such as 7-11 and Maverik have no such proximity restrictions.

² Utah Code §§ 10-8-41.6(7)(a); 17-50-333(7)(a).

14. The Utah Legislature imposed significant fines and penalties on RTSBs for underage tobacco and e-cigarette sales. RTSBs face a \$5,000 fine and immediate thirty-day suspension of their tobacco permit preventing them from selling tobacco or e-cigarette products for their first underage sale.³ A second underage sale by an RTSB within a two-year timeframe is a death sentence for the business via the imposition of a \$10,000 fine and the revocation of their tobacco permit.⁴

15. On the other hand, general tobacco retailers face a relative slap on the wrist for underage sales.⁵ A general tobacco retailer's first violation results in a \$1,000 fine with no suspension of its tobacco permit and a second violation within a year imposes a fine of just \$1,500.⁶ There is no action taken against a general tobacco retailer's tobacco permit until its third underage sale violation in two years via a \$2,000 fine and a 30-day permit suspension.⁷

16. A general tobacco retailer's tobacco permit is revoked only after it has been found to have sold a tobacco or e-cigarette product to an underage person for a fourth time within two years of its previous violations.⁸

³ *Id.* § 26B-7-518(4)(a)-(b).

⁴ *Id.*

⁵ General tobacco owners who sell tobacco or e-cigarette products to underage persons are subject to more harsh penalties in Utah Code section 26B-7-518(3)(a)-(b). However, a general tobacco retailer like Maverik faces no risk of such penalties since its 400+ locations are owned by exclusively by FJ Management, Inc. [/https://maverik.com/pdf/Maverik_Fact_Sheet.pdf](https://maverik.com/pdf/Maverik_Fact_Sheet.pdf)

⁶ Utah Code § 26B-7-518(4)(a)-(b).

⁷ *Id.*

⁸ *Id.*

17. The restrictions and penalties imposed on RTSBs, along with the efforts of the owners of RTSBs in Salt Lake County, have significantly reduced the underage sales violations found by the Salt Lake County Health Department (“**SLCHD**”) in its underage sales stings.

18. In 2023, only two RTSBs failed their compliance checks out of the 135 underage stings performed by SLCHD, resulting in a failure rate of just 1.48%. It was the first violation for both RTSBs.

19. On the other hand, general tobacco retailers in Salt Lake County failed 82 out of the 791 underage stings performed by SLCHD in 2023, resulting in a failure rate of 10.4%. While 63 of the general tobacco retailers were first-time offenders, 15 were second violations and four were third violations. Seventeen of the underage sale violations by general tobacco retailers in 2023 involved e-cigarettes. *See Exhibit A.*⁹

20. As discussed in greater detail below, the youth e-cigarette use rate in Utah is at its lowest point since 2015, all while flavored e-cigarettes have been available to purchase exclusively in RTSBs.

21. Despite the significant decrease in youth e-cigarette use across Utah, and the significant disparities in underage sales violations in Salt Lake County specifically,¹⁰ the Utah Legislature recently pulled the rug out from under RTSB owners by banning flavored e-cigarettes altogether.

⁹ UVBA Board Member Beau Maxon submitted a Government Records Access Management Act (“**GRAMA**”) Request to SLCHD for records relating to underage sales violations and the report attached as Exhibit A was produced by SLCHD in response.

¹⁰ Based upon records obtained via GRAMA Requests from the other local health departments, general tobacco retailers have similarly high underage sting failure rates when compared to RTSB failure rates across Utah.

22. Members of UVBA, including The Smoke House, are RTSBs that generate revenue primarily from the sale of flavored e-cigarette products and will be put out of business by recently enacted legislation prohibiting the sale of such products.

23. Over the last 10 years, the Utah Legislature has either considered or enacted approximately 30 bills governing e-cigarettes and RTSBs.

24. Each legislative session, these specialty shops are confronted with new, increasingly restrictive regulations—many of which encroach on their constitutionally protected rights.

25. Most recently, the Legislature enacted SB 61.

26. UVBA brings this lawsuit and request for declaratory and injunctive relief on behalf of itself and its members who will be irreparably harmed by the enforcement of SB 61.

SB 61 - “Electronic Cigarette Amendments”

27. In 2024, the Utah Legislature adopted SB 61 (the “**Electronic Cigarette Amendments**”), which places new restrictions on the types of e-cigarette products that tobacco retailers may sell in the State of Utah. *See Exhibit B.* Those restrictions include, among others, the following:

- a. Beginning January 1, 2025, RTSBs¹¹ are prohibited from selling flavored e-cigarette products (the “**Flavor Ban**”), *see* Utah Code § 76-10-113(2), which

¹¹ Prior to the enactment of SB 61, RTSBs were the only tobacco retailers with legal authority to sell flavored e-cigarette products in the State of Utah. *See* Utah Code § 76-10-113(1) (2020). General retailers were allowed to sell only those products with the taste or flavor of tobacco, mint, or menthol. *See id.* (authorizing only RTSBs to sell flavored e-cigarette products); *see also id.* § 26-62-102(5) (2020) (defining General Tobacco Retailer to be “a tobacco retailer that is not a retail tobacco specialty business”). In 2024, the Utah Legislature amended the definition of flavored electronic cigarette products to now include mint. *See id.* § 76-10-101(7)(b) (2024). The

include products that are labeled or have “the taste or smell any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, herb, spice, or mint,” *id.* § 76-10-101(7)(b).

- b. The only exempt flavors are “tobacco or menthol.” *Id.* § 76-10-101(7)(c). As of January 1, 2025, the sale of a flavored e-cigarette is punishable as a class C misdemeanor for a first offense and a class B misdemeanor for a second offense. *Id.* § 76-10-113(4).
- c. Beginning January 1, 2025, all tobacco retailers are prohibited from selling any e-cigarette products that are not premarket authorized for pending authorization from the Food and Drug Administration (the “**FDA**”). *See id.* § 76-10-113(3).
- d. Notwithstanding a product’s premarket or pending status, tobacco retailers are banned from selling any e-cigarette product containing greater than 4.0% nicotine by weight or with a nicotine concentration of 40 milligrams per milliliter (the “**Nicotine Regulation**”). *See id.* § 76-10-101(16)(b).

28. Utah Code Section 26A-1-131 is the primary enforcement mechanism for the Flavor Ban and Nicotine Restriction. Importantly, the Electronic Cigarette Amendments do not contain a severability provision.

29. To ensure compliance with the Flavor Ban and the Nicotine Regulation, the Utah Legislature created a registry that requires manufacturers to submit to the Tax Commission a certification form for every e-cigarette product sold in the State. *See id.* § 59-14-810(1)-(2).

effect of this amendment is that tobacco and menthol are the only flavors that may be legally sold in the State.

30. The form must list the nicotine-content level by percentage and any flavors contained in the product, and it must attach proof that the e-cigarette product is premarket authorized or pending authorization by the FDA. *Id.* § 59-14-810(3)(a).

31. The manufacturer must annually recertify the accuracy of the information and pay a fee for every e-cigarette product on the registry that it manufactures. *Id.* § 59-14-810(3)(d).

32. DHHS must review the certification forms and determine which e-cigarette products should be on the registry. *Id.* § 59-14-810(4).

33. Beginning January 1, 2025, it is illegal to sell any e-cigarette product not on the registry. *Id.* § 59-14-810(7).

34. Retailers who violate this provision and sell unregistered e-cigarette products face civil penalties, including fines and licensure suspension. *See id.* § 59-14-810(8). Repeated violations expose retailers to liability for deceptive acts or practices. *Id.* (citing *id.* § 13-11-4 & 13-11a-3).

35. The Tax Commission was required to make the registry publicly available on its website by October 1, 2024. A current version of the e-cigarette registry can be found on the Taxpayer Access Point webpage (https://tap.tax.utah.gov/TaxExpress/_/#2).

36. As of December 11, 2024, the registry includes 72 approved e-cigarette products from only six manufacturers. Upon information and belief, at least some of the products listed on the registry have not received PMTA authorization by the FDA.

37. The Tax Commission, DHHS, local health departments (such as the SLCHD), and the Attorney General are instructed to share information to ensure compliance with and

enforcement of provisions establishing the e-cigarette product registry. *See id.* § 59-14-810(9); *see also id.* § 26A-1-131.

38. Additionally, the Tax Commission and DHHS are granted discretion to promulgate administrative rules to implement the registry. *Id.* § 59-14-810(13).

39. DHHS recently proposed Administrative Code Rules R384-324 and R384-415 to align with SB 61 (the “**2024 Administrative Rules**”). Among other amendments, the proposed rules redefine RTSB, cap nicotine content for e-cigarette products, and prohibit retailers from selling any e-cigarette products that are not included on the registry.

40. Local health departments, as defined in Utah Code section 26A-1-102(6), are vested with primary authority to ensure that retailers comply with the e-cigarette registry. They may “examine the books, papers, and records of a retailer” and conduct warrantless searches of “the premises and all desks, safes, vaults, and other fixtures and furniture contained in or upon the premises for the purpose of ascertaining whether an e-cigarette product is held or possessed” in violation of Utah law. *Id.* § 26A-1-131(1). Local health departments are then required to immediately embargo, at the retailer’s expense, all prohibited e-cigarette products. *Id.* § 26A-1-131(e)–(f).

41. The Utah Legislature’s intended purpose of SB 61 is to curb youth e-cigarette use.

42. When speaking in favor of SB 61 before the Senate Health and Human Services Committee on February 2, 2024, Senator Jennifer Plumb, the sponsor of SB 61, submitted a handout titled “Facts, Figures, and Statistics Supporting a Ban” into the record. *See Exhibit C.*

43. Senator Plumb’s handout references “kids” twice, “young people” twice, and “teens” three times.

44. Senator Plumb's handout referenced "adults" only twice in an inaccurate statistic claiming that "9.7% of Utah high school students reported they had vaped compared to 6.8% of adults."¹²

45. During legislative debate, Senator Plumb acknowledged that legislative amendments would harm small business, stating, "unfortunately, . . . there are business that are going to have to look to change their models if we take flavors out." (Utah Senate, General Session, Feb. 9, 2024).

46. When speaking in favor of SB 61, Senator Curtis Bramble argued, without any supporting authority, that RTSBs have failed to take measures to prevent minors from accessing e-cigarette products even under less strict regulatory schemes. (*Id.*) In light of the regulatory requirements imposed upon RTSBs, Senator Bramble's statement is categorically inaccurate.

SB 61 is Premised on Misinformation and Inaccurate Statistics

Flavored E-Cigarette Products are a Less Harmful Alternative to Traditional Cigarettes

47. Although many of the public-facing statements of DHHS insinuate that e-cigarettes are as harmful as combustible cigarettes, Dr. Borski acknowledged that DHHS knows that e-cigarettes represent a harm reduction over combustible cigarettes. (*See Compl. ¶ 171.*)

48. After acknowledging that e-cigarettes are less harmful than combustible cigarettes, Dr. Borski was asked why DHHS does not publicize the fact that e-cigarettes are less harmful than combustible cigarettes. (*Id. ¶ 172.*) Dr. Borski's response was that DHHS does not endorse harm-reduction as a strategy to help adult smokers quit smoking combustible cigarettes. (*Id.*)

¹² DHHS' previous inaccurate representations of the comparable youth and adult e-cigarette use is discussed in greater detail *infra*.

49. In promulgating previous administrative rules, DHHS cited “Eaton DL *et al.*, 2018; HHS, 2010b” (the “**Eaton Study**”), which is nearly 800 pages and goes into significant detail about the relative risks of combustible cigarettes and e-cigarettes. (*Id.* ¶¶ 173-174.)

50. In addressing the comparative risks of e-cigarettes and combustible cigarettes, the Eaton Study outlines the stark reduction in toxicants inhaled by e-cigarette users, stating the “the toxicants emitted were from 82 to more than 99 percent lower in the e-cigarette aerosol than from the combustible tobacco cigarette smoke.” (*Id.* ¶ 175.)

51. The Eaton Study explicitly rejected the broad conclusion that nicotine content is the sole determiner of an e-cigarette user’s exposure to nicotine, stating, “As with combustible tobacco cigarettes, machine-derived nicotine yield of e-cigarettes is not necessarily predictive of users’ systemic exposures to nicotine.”¹³ (*Id.* ¶ 176.)

52. Chapter 8 of the Eaton Study titled “Dependence and Abuse Liability” concluded that the risk of nicotine dependence for e-cigarette users is lower than traditional combustible tobacco cigarette users:

Conclusion 8-2. There is moderate evidence that risk and severity of dependence are lower for e-cigarettes than combustible tobacco cigarettes.

Finding: There are several supportive findings from fair-quality studies with very few or no credible opposing findings. A general conclusion can be made, but limitations, including chance, bias, and confounding factors, cannot be ruled out with reasonable confidence.

Eaton Study (emphasis added).¹⁴

¹³ The foregoing study can be accessed at <https://www.ncbi.nlm.nih.gov/books/NBK507191/>.

¹⁴ The foregoing study can be accessed at <https://www.ncbi.nlm.nih.gov/books/NBK507178/>

53. The Eaton Study's chapter concerning Dependence and Abuse Liability concluded that traditional combustible tobacco cigarettes may be more likely to induce nicotine addiction than e-cigarettes, stating:

However, it is also possible that e-cigarettes may not produce symptoms of dependence, or that they produce dependence, but at a risk that is significantly lower than combustible tobacco cigarettes.

...

In addition, non-nicotine pharmacological components of combustible tobacco smoke (e.g., monoamine oxidase inhibitors) and other additives may also contribute to the dependence risk caused by combustible tobacco cigarettes (Fagerström, 2012); these compounds may not be present in e-cigarette aerosol. Hence, whether e-cigarettes cause dependence and what the relative magnitude of risk is relative to combustible tobacco cigarettes are questions that cannot be answered solely by the translation of knowledge about nicotine and combustible e-cigarettes and necessitate a review of the empirical evidence.

Id. (emphasis added).

54. The Eaton Study also concluded that nicotine dependence "would be strongly influenced by, but not entirely caused by, nicotine *per se.*" *Id.* (emphasis added).

55. Regarding current combustible cigarette smokers, the Eaton Study found that, "Individuals with considerable histories of smoking report using e-cigarettes to alleviate nicotine withdrawal caused by their cessation of combustible tobacco cigarettes or to satisfy cravings for such cigarettes." *Id.*

56. The Eaton Study confirms that, based upon current scientific literature, the use of e-cigarettes is significantly less harmful to users than the use of traditional combustible tobacco cigarettes, to-wit:

The cancer risk associated with the use of electronic cigarettes hypothetically would be expected to be less than combustible tobacco cigarettes based on the rationale that e-cigarettes include nicotine from tobacco—but not all the other tobacco constituents—and **would therefore result in a reduced burden of carcinogens delivered to the user.**

See, Eaton Study—Cancers.¹⁵ (emphasis added).

57. Dr. Borski acknowledged that the Eaton Study found that people suffering from lung diseases linked to combustible cigarettes who cannot or do not want to quit and instead switch to e-cigarettes see lung function improvements.

Former Adult Smokers Rely on E-Cigarette Products to Stop Smoking

58. There are between 150,000 and 175,000 adult combustible cigarette users in Utah and smoking combustible cigarettes claims the lives of more than 1,300 Utahns every year.¹⁶ DHHS knows that, for those combustible cigarette smokers who cannot quit or do not want to quit smoking cigarettes, e-cigarettes represent a valuable and viable harm reduction tool. (See Compl. ¶ 4.)

59. UVBA’s members are regularly told by their adult customers that they have transitioned completely away from combustible cigarettes with the help of e-cigarettes, largely through the use of flavored e-cigarettes. (See Affidavit of Michael Deighan (“**Deighan Aff.**”), attached hereto as Exhibit D ¶ 20.)¹⁷ Without flavors, some customers have said they would return to traditional cigarettes. (*Id.*)

15. The foregoing study can be accessed at <https://www.ncbi.nlm.nih.gov/books/NBK507174/>

16 <https://ibis.utah.gov/ibisph-view/indicator/view/CigSmokAdlt.SA.html>

17 The Deighan Affidavit was originally filed and attached to the TRO filed in the State Court action.

60. The Electronic Cigarette Amendments will prevent adult e-cigarette users, many of whom have used flavored e-cigarettes as a harm reduction strategy to quit smoking combustible cigarettes, from obtaining flavored e-cigarettes through lawful means. (*See id.* (declaring that some customers will travel out of state to obtain flavored e-cigarette products from Nevada or Wyoming).)

61. Instead, current adult flavored e-cigarette users will be driven back to smoking more harmful combustible cigarettes, forced to obtain flavored e-cigarettes out of state, or turn to the black market to obtain flavored e-cigarettes. (*See id.*)

62. Contrary to the Utah Legislature's perception that adults do not use flavored e-cigarettes, the vast majority of adult e-cigarette users consume flavored e-cigarettes. (*See Affidavit of Kyle Bertagnolli ("Bertagnolli Aff.") ¶¶ 9–10*, attached hereto as Exhibit E (declaring that flavored e-cigarette products account for sales for 89% of e-cigarette sales for surveyed RTSBs).)¹⁸

Youth Smoking has Significantly Declined

63. On September 5, 2024, the United States Centers for Disease Control (the "CDC") published a press release titled "Youth E-Cigarette Use Drops to Lowest Level in a Decade," stating that there was a "a significant drop in the number of U.S. middle and high school students who reported current (past 30 days) e-cigarette use—a decrease from 2.13 million (7.7%) youth in 2023 to 1.63 million (5.9%) youth in 2024." (*See Compl. ¶ 114 & n.27.*)

64. Youth use of e-cigarettes has also been in decline in Utah. (*Id. ¶ 115.*) Every two years, the DHHS releases a Student Health and Risk Prevention Survey ("SHARP Survey"). (*Id.*)

¹⁸ The Bertagnolli Affidavit was originally filed and attached to the TRO filed in the State Court action.

65. Based on SHARP Survey data from 2023, the rate of youth use of e-cigarettes has been in decline across all age groups since 2019 and is lower than 2015 levels—while flavored electronic cigarettes have been available in RTSBs. (*Id.* ¶ 118.)

66. The 2023 SHARP Survey does not include the 2019 and 2021 historical data regarding youth e-cigarette use. (*Id.* ¶ 119.) DHHS’ excluded comparable youth e-cigarette use from previous SHARP Surveys because it claimed the 2021 SHARP Survey questions did not differentiate between vaping nicotine and vaping marijuana. (*Id.*) However, the underlying survey questions regarding “current” youth e-cigarette use in both the 2021 and 2023 SHARP Survey were identical. (*Id.* ¶ 120.)

67. Comparing the 2021 and 2023 SHARP Survey Summary Tables, rather than the charts published in the SHARP Survey, demonstrates that Utah has seen significant reductions in youth e-cigarette use on at least 1 day during the previous 30 days from 9.7% to 5.7%. (*Id.* ¶ 121.)

68. DHHS often misleadingly uses the terminology of “current” youth e-cigarette use to describe “Past 30-day use.” (*Id.* ¶ 122.)

69. The SHARP Survey tracks three different rates of youth e-cigarette use: (i) Youth who “currently used an electronic vapor product . . . on at least 1 day during the 30 days before the survey”; (ii) Youth who “currently used electronic vapor products frequently (on 20 or more days during the 30 days before the survey); and (iii) Youth who “currently used electronic vapor products daily (on all 30 days during the 30 days before the survey). (*Id.*)

70. A person unfamiliar with the underlying data would assume that “current” e-cigarette use would be more akin to the definition used for adults (*i.e.*, some or most days), not

to the actual definition of a “current” youth e-cigarette user who used an e-cigarette one time in the last 30 days. (*Id.* ¶ 123.)

71. In 2021, the SHARP Survey found that 9.7% of youth reported “current” e-cigarette use, but only 2.7% of youth reported using e-cigarettes 20 or more days during the past month. (*Id.* ¶ 124.) Daily youth e-cigarette use in 2021 was 2.2%. (*Id.*)

72. On August 21, 2024, Mr. Ainsworth, testified before the Health and Human Services Interim Committee (“**HHS Committee**”) that a 1% decrease per year in youth e-cigarette use is the “gold standard”:

One of the things I was just looking at our current rates, vaping rates, in 2019. Before this program was created, the youth rate, not daily use rate, but current use rate is the way its defined, was 12.4%. Currently it's at 7.4% and that was the rate that we had last year with the SHARP Survey. Generally when it comes to tobacco prevention and control work, a one percent decrease per year is like the gold standard and so if we figure out where we were then where we are now we are on track to do, we’re doing great things and it looks like that rate is continuing to go down. (Emphasis added.)

(*Id.* ¶ 126.)

73. Based upon Mr. Ainsworth’s testimony before the HHS Committee, Utah has exceeded the “gold standard” because youth e-cigarette use at least one day in the last 30 days fell 4%, from 9.7% in 2021 to 5.7% in 2023. (*Id.* ¶ 127.)

74. Despite substantial progress in reducing youth e-cigarette use, the 2023 SHARP Survey reveals that youth’s perception of their peers’ e-cigarette use is five times higher than actual youth e-cigarette use. (*Id.* ¶ 128.)

75. IBIS likewise conflates “current” youth e-cigarette use and “current” adult e-cigarette use, despite acknowledging that the two definitions measure different metrics. (*Id.* ¶ 129 & n.31.)

76. Although IBIS acknowledges that “current” e-cigarette use is defined differently for youth and adults, and that the SHARP Survey tracks “frequent” and “daily” youth e-cigarette use, IBIS still uses the relative rates of “current” youth and adult e-cigarette use on its website when the two metrics have different meanings. (*Id.* ¶ 130.)

77. While DHHS has previously expressed concerns that youth e-cigarette use would lead to an increase in Utah’s youth smoking combustible cigarettes, Utah’s youth combustible cigarette use rates have continued to decline while flavored e-cigarettes have been available in RTSBs. (*Id.* ¶ 131.)

78. According to the 2023 SHARP Survey, since 2019, lifetime use of combustible cigarettes by Utah’s youth has decreased from 6.9% to 5%, while past 30-day use has decreased from 1.2% to 0.7%. According to IBIS, youth combustible cigarette use in Utah is currently the lowest in over three decades. (*Id.* ¶ 132.)

Utah Government Officials Have Misrepresented the Youth Vaping Statistics

79. DHHS has combined youth vaping of nicotine and marijuana, not just before the HHS Committee but in press releases, driving the claimed “current” “vaping” rate from the 5.7% reported in the raw SHARP Survey data up to 7.4%. (Compl. ¶ 151.)

80. DHHS has also used the “current” use definition to misinform the public regarding youth e-cigarette use rates in Utah. DHHS’ anti-vaping campaign “See Through the Vape”

exclusively targets Utah radio and television with advertisements and points to seethroughthevape.org. (*Id.* ¶ 152.)

81. Until the end of 2022, seethroughthevape.org erroneously compared “current” adult e-cigarette use with “current” youth e-cigarette use, asserting that youth e-cigarette use was seven times higher than adult use.¹⁹ (*Id.* ¶ 153.)

82. However, the actual comparable rate from 2021 was 6.8% of adult e-cigarette use compared to a youth use rate of either 2.7% of frequent users or 2.2% of daily users (*i.e.*, teens were about 1/3 as likely to use e-cigarettes as adults). (*Id.* ¶ 154.)

83. In testimony, Dr. Borski acknowledged that seethroughthevape.com appeared to be misrepresenting the data comparing e-cigarette use amongst youth and adults in Utah. (*Id.* ¶ 155.)

84. The misuse of the “current” youth e-cigarette use rhetoric is not limited to DHHS. (*Id.* ¶ 156.) During the Senate committee on hearing on SB 61, Senator Jennifer Plumb, the bill’s sponsor, spoke in favor of SB 61:

Well let’s look at what’s actually happening right here today. This is from our SHARP Survey, which is done, you know, across Utah students and they look at that kids across the spectrum and they follow where they are on different substance uses...This will give you an idea, so 6% of our youth in 8, 10 and 12 used vape products in the last 30 days by type of substance, just giving you an idea of where that sits. When I asked the folks at DHHS to give me a right now **there’s probably about 70,000 or 66,950 youth currently active vapers, these are kids that are vaping, nearly 70,000 of our kiddos are already stuck on it.**

(Emphasis added).²⁰

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<https://web.archive.org/web/20220817133953/https://seethroughthevape.org/dangers-of-vaping/>

²⁰ <https://le.utah.gov/av/committeeArchive.jsp?timelineID=246293>

85. Although Senator Plumb stated that the 66,950 figure was from DHHS, DHHS's website, [seethroughthevape.org](https://seethroughthevape.org/dangers-of-vaping/) uses a significantly lower statistic, stating that "over 38K Utah teens have tried e-cigarettes."²¹

86. DHHS appears to have updated [seethroughthevape.org](https://seethroughthevape.org/dangers-of-vaping/) after Dr. Borski's testimony in 2022, but there remains blatant misinformation regarding e-cigarettes on DHHS' website. (*Id.* ¶ 160.)

87. For instance, <https://seethroughthevape.org/dangers-of-vaping/> identifies EVALI as a "New Lung Disease Linked to Vaping." (*Id.* ¶ 161.)

88. However, DHHS knows that EVALI was caused by black market THC cartridges—not flavored e-cigarettes sold in regulated stores. (*Id.* ¶ 162.) Indeed, in her testimony, Dr. Borski acknowledged seethroughthevape.org links EVALI to nicotine e-cigarettes when there was no link between EVALI and e-cigarettes sold in regulated stores. (*Id.* ¶¶ 162-163.)

89. Investigations by the CDC concluded that EVALI was caused by the use Vitamin E Acetate in black market, unregulated THC vaping cartridges, not flavored e-cigarettes. (*Id.* ¶ 164.)

90. Unfortunately, seethroughthevape.org is not the only place that DHHS has misinformed the public regarding e-cigarettes. (*Id.* ¶ 165.) During the Administrative Rules Review Committee meeting on May 17, 2021, DHHS provided a PowerPoint presentation regarding DHHS' efforts to reduce nicotine use in Utah. (*Id.*)

91. Part of DHHS' presentation on May 17, 2021, stated that a JUUL Pod with 3% a nicotine concentration "equals the same amount of nicotine inhaled in a pack of 20 cigarettes." (*Id.*

²¹ <https://seethroughthevape.org/dangers-of-vaping/>

¶ 166.) DHHS' reference for the statistic that a 3% JUUL pod was the equivalent of a pack of cigarettes was TruthInitiative.org. (*Id.*)

92. Mr. Ainsworth also signed a sworn declaration (that was filed with the Third District Court) stating that a 3% JUUL pod had the equivalent nicotine of a pack of cigarettes in DHHS' efforts to support the Three Percent Rule. (*Id.* ¶ 167.)

93. The TruthInitiative.org link DHHS cited in the Administrative Rules Review Committee and referenced in Mr. Ainsworth's Declaration cited to JUUL's website, which stated that a JUUL Pod with 5% nicotine was the equivalent of a pack of cigarettes. (*Id.* ¶ 168.) The same information regarding the nicotine content of a 5% JUUL pod containing the equivalent nicotine of a pack of cigarettes was reported in the National Library of Medicine. (*Id.* ¶ 169.)

94. After being confronted by the information from TruthInitiative.org in his deposition, Mr. Ainsworth testified that it was possible that DHHS had misrepresented that a 3% JUUL pod was the equivalent of a pack of cigarettes. (*Id.* ¶ 170.)

The Federal Regulatory Scheme Governing Tobacco Products

95. The United States Congress has already established a comprehensive legislative framework to regulate tobacco products, including, the Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 11-31, 123 Stat. 1776 (June 22, 2009), codified at 21 U.S.C. § 387a–v (the “**Tobacco Control Act**”).

96. The Tobacco Control Act added a new Chapter IX to the federal Food, Drug and Cosmetic Act and significantly altered federal regulation of tobacco products by, for the first time, vesting the FDA with primary regulatory authority to regulate tobacco products. *See* 21 U.S.C. § 387a.

97. The stated purpose of the Tobacco Control Act is to “ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco” and “authorize the Food and Drug Administration to set national standards controlling the manufacture of tobacco products.”

98. Pursuant to the Tobacco Control Act, the FDA may issue and enforce various tobacco product regulations, *id.* § 387 note (1), (10), while also safeguarding “the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers,” *id.* § 387 note (7).

99. The Tobacco Control Act empowers the FDA to establish national “tobacco product standards” it deems “appropriate for the protection of public health.” *Id.* §§ 387g(a)(3)(A), 387j(c)(2).

100. In making this determination, the FDA considers scientific and other evidence concerning, among other things, “the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard,” *id.* § 387g(a)(3)(B)(i)(I), and “the countervailing effects of the tobacco product standard . . . such as the creation of a significant demand for contraband,” *id.* § 387g(b)(2).

101. The Tobacco Control Act contains a specific federal tobacco product standard that prohibits *cigarettes* that “contain, as a constituent . . . or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or its smoke.” *Id.* § 387g(a)(1)(A).

102. Congress did not enact a similar prohibition for flavored smokeless tobacco and other non-cigarette tobacco products. *Id.*

103. Section 387p of the Tobacco Control Act expressly preempts any state or local regulation that sets forth requirements that are “different from, or in addition to” the Act’s requirements “relating to tobacco product standards.” 21 U.S.C. § 387p(a)(2)(A).

104. Section 387p provides a limited exception for requirements “relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products.” *Id.* § 387p(a)(2)(B).

ARGUMENT

The purpose of preliminary injunctive relief is to “preserve the status quo” until the court can conduct a full hearing on the merits. *N. Arapahoe Tribe v. Hotel*, 808 F.2d 741, 753 (10th Cir. 1987). The status quo is defined as “the last peaceable uncontested status existing between the parties before the dispute developed.” *Monavie, LLC v. Quixtar Inc.*, 741 F. Supp. 2d 1227, 1242 (D. Utah 2009). Thus, a preliminary injunction should issue where a plaintiff demonstrates: “(1) [the movant] will suffer irreparable injury unless the injunction issues; (2) the threatened injury . . . outweighs whatever damage the proposed injunction may cause the opposing party; (3) the injunction, if issued, would not be adverse to the public interest; and (4) there is a substantial likelihood of success on the merits.” *Resolution Trust Corp. v. Cruce*, 872 F.2d 1195, 1198 (10th Cir. 1992); *Greater Yellowstone Coal. v. Flowers*, 321 F.3d 1250, 1255 (10th Cir. 2003). The standard for a temporary restraining order is the same as a preliminary injunction. *MonaVie, LLC v. Wha Lit Loh*, No. 2:11-cv-265, 2011 WL 1233274, at *3 (D. Utah Mar. 31, 2011). Plaintiffs

have satisfied all the necessary elements to be granted their requested injunctive relief, protecting them from the imminent and irreparable threat that the Electronic Cigarette Amendments pose to their businesses and customers.

I. PLAINTIFFS ARE SUBSTANTIALLY LIKELY TO PREVAIL ON THE MERITS OF THEIR UNDERLYING CLAIMS.

Plaintiffs' Complaint challenges the Electronic Cigarette Amendments on four separate grounds. Plaintiffs are substantially likely to prevail on the merits of each claim.

A. Federal Law Preempts the Flavor Ban.

Pursuant to the Supremacy Clause of the United States Constitution, "state action may be foreclosed by express language in a congressional enactment, by implication from the depth and breadth of a congressional scheme that occupies the legislative field, or by implication because of a conflict with a congressional enactment," *i.e.*, express, field, or conflict preemption. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 541 (2001) (internal citations omitted); *see also* U.S. Const. art. VI. cl. 2.

Relevant here, Congress has enacted the Tobacco Control Act, which vests the FDA with authority to regulate tobacco products and imposes new requirements and restraints on the marketing of such products. *See* 21 U.S.C. § 387a. This federal law expressly and impliedly preempts the Flavor Ban.

1. The Tobacco Control Act Expressly Preempts the Flavor Ban.

The Tobacco Control Act expressly preempts any state or local regulation that sets forth requirements that are "different from, or in addition to" the Tobacco Control Act's requirements (or requirements promulgated by the FDA) "relating to tobacco product standards." 21 U.S.C. § 387p(a)(2)(A) (the "**Preemption Clause**"). The significance of the Preemption Clause is that it

allows tobacco retailers to focus on complying with a single set of product standards rather than grappling with myriad state and local requirements regulating the same products. *See* Tobacco Control Act § 3(3), 123 Stat. at 1781 (codified at 21 U.S.C. § 387 note). The Flavor Ban, set to go into effect on January 1, 2025,²² establishes a “tobacco product standard” that is “different from” and “in addition to” federal requirements related to tobacco product standards and is therefore expressly preempted.

a. The Flavor Ban is a “tobacco product standard.”

The Tobacco Control Act gives the FDA the power to prohibit the sale and distribution of certain tobacco products through the adoption of “tobacco product standards.” *See* 21 U.S.C. § 387g. A tobacco product that does not conform with applicable federal tobacco product standards is an “adulterated” product that may not be sold in the United States. *Id.* §§ 387b(5), 331(a), (c). Both the language of the Act itself and the FDA’s actions confirm that the Flavor Ban constitutes a “tobacco product standard.”

First, under the Tobacco Control Act, “tobacco product standards” include “provisions respecting the . . . additives [and] properties of the tobacco product.” *Id.* § 387g(a)(4)(B)(i). “Additives” include “substances intended for use as a flavoring.” *Id.* § 387(1). Read together, those definitions support the conclusion that a “tobacco product standard” includes any provision respecting “substances intended for use as a tobacco-product flavoring.” *Id.*; *see also id.* § 387g(a)(1)(A).

Congress’ actions support this interpretation. Through the enactment of special rules, Congress has clearly signaled that bans governing the sale of flavored e-cigarette products qualify

²² *See* Utah Code § 76-10-113(2).

as a tobacco product standard because those laws regulate “additives.” Congress has enacted two special rules—one of which prohibits cigarettes that contain a “characterizing flavor” (with the express exception of menthol). *See id.* § 387g(a)(1)(A). The federal ban prohibits “a cigarette or any of its component parts” from “contain[ing], as a constituent . . . or *additive*, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, . . . that is a characterizing flavor of the tobacco product or tobacco smoke.” *Id.* (emphasis added); *see also id.* § 387g(a)(2) (referencing the statutory ban on characterizing flavors in cigarettes as a “tobacco product standard[]”); *id.* § 387g(a)(3) (same). If a ban on all flavored cigarettes except menthol is a tobacco product standard, then a state law or local ordinance that bans all flavored e-cigarette products is a tobacco product standard as well.

The word “properties” in the Tobacco Control Act independently supports the conclusion that regulating e-cigarette flavors creates a tobacco product standard. *See* 21 U.S.C. § 387g(a)(4)(B)(i). A “property” of a product is an “attribute, characteristic, or quality” of the product. Oxford English Dictionary, “Property” (2020), available at <https://www.oed.com>. In turn, the “taste or aroma” of a product is an “attribute, characteristic, or quality” of the product. *See* Webster’s Third 1818 (defining “property” as “an effect that a material object or substance has . . . on one or more of the senses of an observer”); *see also JL Beverage Co., LLC v. Beam, Inc.*, 318 F. Supp. 3d 1188, 1205 (D. Nev. 2018), *aff’d*, 2020 WL 2765083 (9th Cir. 2020) (listing “flavor” as a “characteristi[c] of the vodka”); *McGinnis v. Kellogg USA*, 2007 WL 4766060, at *3 (C.D. Cal. Sept. 19, 2007) (describing “Natural Fruit Flavors” as “characteristics” of Froot Loops).

Unsurprisingly, the FDA considers a tobacco product’s “characterizing flavor” to be a “product property.” Premarket Tobacco Product Applications and Recordkeeping Requirements,

84 Fed. Reg. 50, 566, 50, 637 (proposed Sept. 25, 2019) (“If the product does not have a listed product property, such as . . . characterizing flavor, the application must state ‘none’ for that property”); *see also id.* at 50, 637–42 (requiring “Characterizing flavor(s) (e.g., none, menthol)” to be included on list of “Product properties”). By banning tastes and smells in tobacco products, Utah has regulated the properties of the products, and thus created a tobacco product standard. *See Utah Code § 76-10-113(2); id. § 76-10-101(7).*

Second, the FDA’s use of its rulemaking authority also confirms that a ban on the sale of flavored tobacco products amounts to a tobacco product standard. The FDA has issued several advanced notices of proposed rulemaking in which it contemplated the adoption of “tobacco product standard[s]” banning various flavored tobacco products, including menthol cigarettes and flavored vapor products. *Menthol in Cigarettes, Tobacco Products; Request for Comments*, 78 Fed. Reg. 44, 484, 44,485 (July 24, 2013); *Regulation of Flavors in Tobacco Products*, 83 Fed. Reg. 12,294, 12299 (Mar. 21, 2018); *see also* FDA, Press Release (Nov. 15, 2018) (announcing intent to consider banning menthol cigarettes and flavored cigars). As recently as 2022, the FDA published proposed rules that it planned to issue as “tobacco product standards” that would prohibit “menthol as a characterizing flavor in cigarettes” and “characterizing flavors (other than tobacco) in all cigars and their components and parts. *See* Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26454 (proposed May 4, 2022); Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. 26396 (proposed May 4, 2022). These recent proposals demonstrate that the FDA understands that it has been tasked by the Tobacco Control Act with exclusive authority to regulate the use of tobacco flavors through the enactment of tobacco product standards. This authority extends to flavored e-cigarettes.

In sum, regulations of tobacco flavors are tobacco product standards because they pertain to either “additives” or “properties” of those products. On that basis, the Flavor Ban qualifies as a tobacco product standard because the ban regulates the smell and taste of flavored e-cigarette products. The Flavor Ban states: “[B]eginning on January 1, 2025, it is unlawful for a person to give, distribute, sell, offer for sale, or furnish to any person a flavored electronic cigarette product.” Utah Code § 76-10-113(2). “Flavored electronic cigarette product” means “an electronic cigarette product that is labeled as, or has a taste or smell of any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, herb, spice, or mint.” *Id.* § 76-10-101(7)(b). The only exempt flavors are “tobacco or menthol.” *Id.* § 76-10-101(7)(c).

By banning tastes and smells of e-cigarette products, Utah has regulated the additives and properties of such products and has therefore created a “tobacco product standard.” Utah’s tobacco product standard, if enforced, would be “different from” and “in addition to” the Tobacco Control Act’s standards because the Flavor Ban prohibits the sale of any flavored e-cigarette product. The tobacco product standards announced in the Tobacco Control Act do not ban the sale of flavored e-cigarettes. *See* 21 U.S.C. § 387g. Rather, Congress has prohibited only the sale of flavored cigarettes, and it has left regulation of flavored e-cigarettes to the FDA. *See id.* § 387g(a)(1)(A). Because Utah is attempting to enforce a more-expansive prohibition, the Legislature has enacted a tobacco product standard that is expressly preempted by federal law.²³

²³ Three courts from other jurisdictions have held that local laws banning the sale of flavored tobacco products were not regulations of tobacco product standards and were thus not expressly preempted by the TCA. *See Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence, R.I.*, 731 F.3d 71, 85 (1st Cir. 2013); *U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708 F.3d 428, 436 (2d Cir. 2013); *R.J. Reynolds Tobacco Co. v. Cty. Of Los Angeles*, 471 F. Supp. 3d 1010, 1018 (C.D. Cal. 2020). At least one court disagreed, holding that a city ordinance prohibiting the sale of flavored tobacco products “fits comfortably within the description of tobacco-product

b. The Tobacco Control Act's Savings Clause does not save the Flavor Ban.

“[O]nce the party challenging a regulation or ordinance establishes that it violates [a preemption clause], the burden is properly on the [government] . . . to establish that [the Saving Clause] applies.” *Puerto Rico Tel. Co. v. Mun. of Guayanilla*, 450 F.3d 9, 21 (1st Cir. 2006). The Saving Clause exempts from preemption any state and local “requirements relating to the sale, distribution, possession, . . . exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age.” 21 U.S.C. § 387p(a)(2)(B). The State of Utah cannot carry its burden for at least two separate reasons.

First, the Saving Clause does not encompass state laws and local ordinances that wholly prohibit a product’s sale and distribution based on its failure to comply with tobacco product standards. Instead, the Saving Clause protects more limited laws that regulate the time, place, and manner of the product’s sale or distribution.

Under its plain language, the Saving Clause applies only to “requirements relating to the sale [and] distribution” of “tobacco products.” 21 U.S.C. § 387p(a)(2)(B). Sales “requirements” do not include outright prohibitions. Indeed, the very notion of a sales requirement presumes that the product can be sold under some circumstances. When Congress wanted to give states the authority to prohibit sales of tobacco products, it explicitly said so. A fundamental tenet of statutory interpretation is that clauses must fit “into an harmonious whole.” *Roberts v. Sea-Land Servs., Inc.*, 566 U.S. 93, 100 (2012). Courts must interpret statutes in a manner such that “effect

standards.” See *R.J. Reynolds Tobacco Co. v. City of Edina*, 482 F. Supp. 3d 875, 879 (D. Minn. 2020). That court nonetheless sided with the defendants, holding that the ordinance fell within the scope of the TCA’s Savings Clause. For the reasons set forth herein, those decisions, which are non-binding in this Court, are unpersuasive.

is given to all . . . provisions.” *Corley v. United States*, 556 U.S. 303, 314 (2009). On that basis, the Saving Clause “cannot in reason be construed as” being “inconsistent with the [other] provisions of the act.” *Am. Tel. & Tel. Co. v. Cent. Office Tel., Inc.*, 524 U.S. 214, 227–28 (1998). Instead, the Tobacco Control Act’s preemption-related provisions must be read together.

Under Section 387p(a)(1), Congress preserved states’ authority to enact laws “relating to or prohibiting” sales, except when preempted by the Tobacco Preemption Clause. *Id.* § 387p(a)(1)–(2). Congress’ decision to use “relating to or prohibiting” sales in the Preservation Clause, but to omit “or prohibiting” from an almost identical phrase in the Saving Clause, demonstrates that Congress did not intend for the Saving Clause to be construed as permitting states and localities to enact sales prohibitions. *See Russello v. United States*, 464 U.S. 16, 23 (1983) (“[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.”). Thus, the Saving Clause preserves the traditional authority of state and local governments to regulate how, when, where, and to whom, such products may be sold. It does not preserve state and local governments’ ability to categorically ban the sale of tobacco products that fail to comply with a state or local “tobacco product standard.”

Second, interpreting the Saving Clause to apply to laws that prohibit the sale and distribution of tobacco products altogether violates United States Supreme Court precedent. The Supreme Court has “repeatedly decline[d] to give broad effect to saving clauses where doing so would upset the careful regulatory scheme established by federal law.” *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 870 (2000) (alteration in original) (citation and internal quotation marks omitted). Reading the Saving Clause to allow local sales bans based on a tobacco product’s

ingredients would undoubtedly upset the “careful regulatory scheme” enacted under Tobacco Control Act. *Id.*

If the Saving Clause were read this broadly, the Preemption Clause would be eviscerated. States and localities could always subvert the Preemption Clause by characterizing a “tobacco product standard” as a ban on the sale or distribution of tobacco products that failed to comply with the substance of that standard. For example, the Tobacco Control Act creates a detailed process for premarket review and approval of new tobacco products, 21 U.S.C. § 387j, and then preempts state and local requirements that are “different from, or in addition to” that process, *id.* § 387p(a)(2)(A). Under an expansive reading of the Saving Clause, states and localities could undercut this federal system by prohibiting the sale of any new products that have not been vetted through their own, unique premarket review process. The result would be a patchwork of conflicting standards that would vitiate Congress’ intent that the FDA “set national standards controlling the manufacture of tobacco products and the . . . amount of ingredients used in such products.” Tobacco Control Act § 3(3), 123 Stat. 1782 (codified at 21 U.S.C. § 387 note).

The United States Supreme Court has unanimously rejected a similar attempt by California to use a sales ban to evade federal preemption. *See Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 464 (2012). In *National Meat*, the Court addressed the scope of the preemption clause contained in the Federal Meat Inspection Act, which regulates slaughterhouses. *Id.* at 458. Like the Tobacco Control Act, the Meat Inspection Act has an express preemption clause prohibiting states from promulgating standards that are “in addition to, or different than those made under this [Act],” but allowing states to “mak[e] requirement[s] or tak[e] other action, consistent with this [Act].” *Id.* at 458 & n.3 (quoting 21 U.S.C. § 678). Although the Meat Inspection Act authorized

slaughterhouses to receive and slaughter nonambulatory animals in some circumstances, the California statute imposed a ban on buying or selling nonambulatory animals, which effectively nullified the federal law.

The Court held that the state statute was preempted by the Meat Inspection Act, even though “the [Act’s] preemption clause does not usually foreclose state regulation of the commercial sales activities of slaughterhouses.” *Id.* at 463 (internal quotation marks omitted). In a unanimous decision, Justice Kagen explained that “the sales ban . . . functions as a command to slaughterhouses to structure their operations in the exact way” that California wanted, and that was precluded by the Act. *Id.* at 464. The Court continued, “[I]f the sales ban were to avoid [the Act’s] preemption clause, then any State could impose any regulation on slaughterhouses just by framing it as a ban on the sale of meat produced in whatever way the State disapproved.” *Id.* “That would make a mockery of the [Act’s] preemption provision.” *Id.*

The same is true here. “If [the Flavor Ban] were to avoid the [Tobacco Control Act’s] preemption clause, then any State could impose any regulation on [tobacco product ingredients] just by framing it as a ban on the sale of [tobacco products] produced in whatever way the State disapproved.” *See id.* And as the Supreme Court has observed, “if one State or political subdivision may enact such rules, then so may any other; and the end result would undo Congress’s carefully calibrated regulatory scheme.” *Engine Mfrs. Ass’n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. at 255. The Tobacco Control Act’s Saving Clause does not permit Utah to enact an outright Flavor Ban. This Court should not allow the State of Utah to upset Congress’ design.

2. The Tobacco Control Act impliedly preempts the Flavor Ban.

In addition to being expressly preempted,²⁴ Utah’s ban on flavored tobacco products is impliedly preempted by the Tobacco Control Act because it “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress” in at least two ways. *See Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 373 (2000) (citation omitted).

First, Congress adopted the Tobacco Control Act “to authorize the [FDA] to set national standards controlling the manufacture of tobacco products and the . . . amount of ingredients used in such products.” Tobacco Control Act § 3(3), 123 Stat. 1782 (codified at 21 U.S.C. § 387 note). As explained above, however, allowing state and local governments to ban the sale of tobacco products solely because they contain ingredients that reveal a characterizing flavor would undermine that purpose.

Second, the Flavor Ban would undermine Congress’ and FDA’s judgment that certain flavored tobacco products should remain on the market. One purpose of the Tobacco Control Act is “to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers.” Tobacco Control Act § 3(7), 123 Stat. 1782 (codified at 21 U.S.C. § 387 note); *see also FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 139 (2000) (“[T]he collective premise of the [federal tobacco] statutes is that cigarettes and smokeless tobacco will continue to be sold in the United States[.]”).

²⁴ The existence of an express preemption clause “does *not* bar the ordinary working of [implied] pre-emption principles.” *Hillman v. Maretta*, 569 U.S. 483, 498 (2013) (citation and internal quotation marks omitted); *see also Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 352 (2001) (“[N]either an express preemption provision nor a saving clause ‘bar[s] the ordinary working of conflict preemption principles.’” (alteration in original) (citation omitted)).

For example, Congress expressly decided that menthol cigarettes should remain on the market unless FDA adopted a menthol product standard. *See* 21 U.S.C. § 387g(a)(1)(A), (e). Congress also ordered the Tobacco Products Scientific Advisory Committee to study the issue of menthol cigarettes. *See id.* § 387g(e). On several occasions, the FDA has issued advanced notices of proposed rulemaking when contemplating the adoption of “tobacco product standard[s]” banning various flavored tobacco products, including menthol cigarettes and flavored vapor products. *See* Menthol in Cigarettes, Tobacco Products; Request for Comments, 78 Fed. Reg. 44,484, 44,485 (July 24, 2013); Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12,294, 12,299 (Mar. 21, 2018); *see also* FDA, Press Release (Nov. 15, 2018) (announcing intent to consider banning menthol cigarettes and flavored cigars). In response, the FDA received comments demonstrating that there is no justification—scientific or otherwise—for it to limit or ban menthol cigarettes. As these comments showed, menthol cigarettes do not pose a different health risk from other types of cigarettes, and they do not adversely affect smoking initiation, dependence, or cessation. *See, e.g.*, RAI Services Company, Comment Letter on Advance Notice of Proposed Rulemaking Regarding Menthol in Cigarettes, Tobacco Products (Nov. 22, 2013); RAI Services Company, Comment Letter on Advance Notice of Proposed Rulemaking Regarding Regulations of Flavors in Tobacco Products (July 18, 2018). After receiving these comments, the FDA chose not to propose a menthol product standard for cigarettes.

Through this process, the FDA obtains important evidence to inform its scientific judgment about tobacco products. The FDA can then determine which certain products, including flavored e-cigarettes should remain on the market. If allowed to stand, the Flavor Ban would create a substantial obstacle to FDA’s charge to set national standards for the manufacturing or ingredients

included in tobacco products. Accordingly, the Flavor Ban is impliedly banned by the Tobacco Control Act.

B. The Inspection Program Violates the Fourth Amendment to the United States Constitution.

Plaintiffs have a substantial likelihood of succeeding on the merits of their claim that the Inspection Program violates business owners' Fourth Amendment rights. The Fourth Amendment to the United States Constitution, made applicable to the states by the Fourteenth Amendment, protects “[t]he right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures.” U.S. Const. amend. IV; *see also id.* amend XIV. It further provides that “no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.” *Id.* Relying on this constitutional language, the United States Supreme Court has repeatedly held that warrantless searches conducted outside of the judicial process “are *per se* unreasonable . . . subject only to a few specifically established and well-delineated exceptions.” *City of Los Angeles, Calif. v. Patel*, 576 U.S. 409, 419 (2015) (alteration in original) (citation omitted).

The Supreme Court has extended these protections to commercial premises as well as private homes. *New York v. Burger*, 482 U.S. 691, 699 (1987). Business owners therefore possess a reasonable expectation of privacy in commercial property for both traditional police searches and administrative inspections designed to enforce statutory regulations. *Id.* at 699–700. There is a narrow exception to the warrant requirement for closely regulated businesses. This exception to the warrant requirement is known as either the “*Colonnade-Biswell* doctrine” or the “pervasively regulated industry” exception. *See, e.g., United States v. Biswell*, 406 U.S. 311 (1972) (regulating

businesses engaged in sale of firearms); *Colonnade Catering Corp. v. United States*, 397 U.S. 72 (1970) (regulating businesses engaged in sale of liquor).

For a warrantless search of a closely regulated business to be reasonable and thus constitutional under the Fourth Amendment, first, “there must be a ‘substantial’ government interest that informs the regulatory scheme pursuant to which the inspection is made.” *Burger*, 482 U.S. at 702 (citations omitted). Second, the “warrantless inspections must be necessary to further [the] regulatory scheme.” *Id.* at 703 (alteration in original) (citation omitted). Finally, the search must be conducted pursuant to a statutory scheme or inspection program whose terms provide “a constitutionally adequate substitute for a warrant.” *Id.* (citation omitted). As to the first prong, Plaintiffs do not dispute that the State of Utah has a substantial interest in curbing youth’s access to and use of tobacco and e-cigarette products. Indeed, Plaintiffs share that same interest. But the Inspection Program permitting warrantless regulatory inspections of the entire premises of tobacco retail stores fails to meet the second and third prong and thus authorizes local health departments to conduct unconstitutional searches and seizures in violation of the Fourth Amendment to the United States Constitution.

The Utah Legislature created an entirely new statutory subsection in Utah Code Section 26A-1-131, which is titled “Electronic cigarette registry enforcement.” The warrantless searches authorized in Utah Code Section 26A-1-131 are the enforcement mechanism for the Flavor Ban and the Nicotine Restriction. Utah Code Section 26A-1-131 does not contain a severability provision. In determining whether the Electronic Cigarette Amendments can survive if the unconstitutional warrantless search provisions are severed, this Court must “turn to the statute itself, and examine the remaining constitutional portion of the statute in relation to the stricken

portion.” *Vega v. Jordan Valley Med. Ctr., LP*, 2019 UT 35, ¶ 17, 449 P.3d 31, 37. And here, this Court must turn to controlling state law in deciding the severability argument. *See Leavitt v. Jane L.*, 518 U.S. 137, 139 (1996). (“Severability is of course a matter of state law.”) The Electronic Cigarette Amendments can only withstand constitutional challenge if “the remainder of the statute is operable and still furthers the intended legislative purpose.” *Id.* Inasmuch as there is no severability provision found in the relevant statutes and the warrantless search provisions violate Plaintiffs’ constitutional rights, the remaining provisions of the Electronic Cigarette Amendments will be rendered inoperable upon a determination that the warrantless search provisions are unconstitutional and must be enjoined.

1. Warrantless onsite inspections of Plaintiffs’ retail locations are not necessary to further Utah’s regulatory scheme governing the sale of e-cigarette products.

As to the second prong, the State of Utah does not need to conduct warrantless onsite inspections of tobacco retail stores to further its stated interest in curbing youth vaping. As evidenced by the statistics from SLCHD, Salt Lake County RTSBs failed only 1.48% of the underage sales stings in 2023 compared to 10.4% of Salt Lake County general tobacco retailers. The disparity between the rates of underage sale violations for general tobacco retailers and RTSBs is especially stark when considering that general tobacco retailers cannot lawfully sell flavored e-cigarettes. The fact that the percentage of general tobacco retailers failing SLCHD’s underage sales was seven times greater than RTSBs in 2023 disproves any claim that RTSB’s sale of flavored e-cigarettes increases youth e-cigarette use. Moreover, two of the brands that youth report using the most—JUUL and Vuse—do not currently market flavors other than menthol and tobacco. Simply put, restricting flavored e-cigarettes to the more controlled environment of RTSBs where patrons

must be over 21 to enter, and imposing stiffer penalties for underage sales, has already resulted in reduced underage flavored e-cigarette sales.

In fact, all available evidence available on youth e-cigarette use, both in Utah and nation-wide, demonstrates that the draconian measures in SB 61 are unnecessary to reduce youth e-cigarette use. In October 2024, the FDA and the CDC released findings from the 2024 National Youth Tobacco Survey, which revealed a “significant drop in the number of students who reported current e-cigarette use” between 2023 and 2024.²⁵ Utah has experienced a similar trend with declining use of e-cigarette products. As further explained above, DHHS releases the SHARP Survey every two years. The most-recent SHARP Survey from 2023 found that the rate of youth use of e-cigarette products has declined across all age groups since 2019 and is lower than 2015 levels. This data directly refutes claims by lawmakers that youth vaping is increasing and that that trend is the result of RTSBs’ noncompliance with prior regulations governing e-cigarette products. *See supra ¶ 45.* It was this misguided allegation of noncompliance that spurred the Utah Legislature to adopt the Flavor Ban and corresponding Inspection Program to enforce it.

Plaintiffs have complied with regulations, and the reduction in youth vaping is a testament to that compliance. *See* Bertagnolli Aff. ¶ 5; Deighan Aff. ¶¶ 7–10. As the industry has been increasingly regulated, Plaintiffs have adopted policies and procedures to adhere to those regulations, such as electronic age verification to ensure customers are at least 21 years of age. *Id.* Plaintiffs do not want to sell to minors and have a strong interest in aiding the State’s goal of

²⁵ U.S. FOOD & DRUG ADMINISTRATION, Results from the Annual National Youth Tobacco Survey, <https://www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey#Previous%20National%20Youth%20Tobacco%20Survey> (last visited Nov. 21, 2024).

restricting youth access to e-cigarette products. Claims that Plaintiffs are financially motivated to sell e-cigarettes to underage youth are misguided and unsupported. RTSBs that violate state and local regulations governing the sale of such products face severe penalties, including fines that increase from \$5,000 on a first violation to \$10,000 on a second violation and permit suspension followed by revocation on a second offense. Utah Code § 26B-7-518(4)(a)–(b). Any speculative financial gain through these unlawful sales is drastically outweighed by the risk of losing the ability to operate and all revenue generated from that retail location.

Current data unequivocally establishes that Utah’s interest in shielding youth access to e-cigarette products does not necessitate warrantless searches. Youth vaping has been dropping significantly even while it has been legal to sell flavored e-cigarette products. These additional restrictions banning flavors and authorizing warrantless searches are excessive, and they threaten the gains that society has made to reduce the use of traditional cancer-causing cigarettes and other tobacco products. *See infra ¶ 58.* For these reasons, the Inspection Programs fails to satisfy the second *Burger* prong.

2. Utah’s inspection program is overbroad because it permits inspectors to search anywhere on Plaintiffs’ premises, including locations where inventory is not stored.

As to the third prong, a regulatory statute does not provide a constitutionally adequate substitute for a warrant *unless* it (1) “advise[s] the owner of the commercial premises that the search is being made pursuant to the law and has a properly defined scope,” and (2) “limit[s] the discretion of the inspecting officers.” *Burger*, 482 U.S. at 703. Here, the Inspection Program fails *Burger*’s requirement that the warrantless inspection regime be “carefully limited in time, place, and scope.” *Id.* at 703 (quoting *Biswell*, 406 U.S. at 315).

In relevant part, the statute permits “[a] local health department” to “inspect the premises and all desks, safes, vaults, and other fixtures and furniture contained in or upon the premises for the purpose of ascertaining whether an e-cigarette product is held or possessed in violation of Section 59-14-810.” Utah Code § 26A-1-131(1)(b). Onsite inspections are permissible “at any time during ordinary business hours.” *Id.*

The Inspection Program does not provide careful limitations as to place and scope of inspections and thus fails to restrain an inspecting officer’s unfettered discretion. *See Burger*, 482 U.S. at 711. Even though the Inspection Program specifically identifies locations that may be inspected (e.g., desks, safes, vaults, and other fixtures and furniture), the permissible scope of inspections is significantly broader than that. Section 26A-1-131(1)(b) is written in the conjunctive and permits local health departments to inspect “the premises *and* desks, safes, vaults, and other fixtures and furniture contained in or upon the premises.” (Emphasis added.) In other words, no portion of the premises is afforded constitutional protection even if it is a location where e-cigarette products are not and cannot be stored. *See Marshall v. Barlow’s, Inc.*, 436 U.S. 307 (1978) (holding that OSHA regulation was overly broad because it allowed inspectors to search areas where there was no reason to believe workplace safety violations were likely to be found).

The Inspection Program is not necessary to ensure compliance with SB 61. The existing regulatory framework already allows local health departments like SLCHD to conduct undercover “stings” at both RTSBs and general tobacco retailers, and harsh penalties are imposed against any retailer that makes a sale in violation of applicable laws and regulations. Moreover, there is no evidence or suggestion by the State of Utah that RTSBs are selling contraband products to customers, or storing said contraband products in locked safes, offices, vaults, closets, desks, or

furniture. Indeed, Plaintiffs submit that the vast majority of UVBA members, including The Smoke House, do not store any e-cigarette products (including flavored products) in these areas, especially during ordinary business hours when inspections are authorized. Bertagnolli Aff. ¶¶ 16–19; *see also* Deighan Aff. ¶ 18. Plaintiffs, including The Smoke House, store these products on open shelves viewable to customers and inspectors alike. *See id.* As such, there is no indication that warrantless searches of both the public and private areas of RTSBs are necessary to enforce SB 61 or any existing tobacco sales laws. Because the Inspection Program is overly broad, it is unconstitutional. The Court should enjoin Defendants from conducting inspections pursuant to Section 26A-1-131 pending further litigation on the merits.

C. The Inspection Program Violates Article I, Section 14 of the Utah Constitution.

Even if the Court determines that the Inspection Program does not violate the Fourth Amendment, Plaintiffs are substantially likely to prevail on their claim under the Utah Constitution. Article I, section 14 of the Utah Constitution guarantees that

The right of the people to be secure in their persons, houses, papers and effects against unreasonable searches and seizures shall not be violated; and no warrant shall issue but upon probable cause supported by oath or affirmation, particularly describing the place to be searched, and the person or thing to be seized.

Although this language is nearly identical to the Fourth Amendment, the Utah Supreme Court has repeatedly signaled that, in certain situations, Article I, section 14 provides more robust protections than its federal counterpart. *See State v. DeBooy*, 2000 UT 32, ¶ 12, 996 P.2d 546 (stating that the Utah Supreme Court “will not hesitate to give the Utah Constitution a different construction [than the United States Supreme Court’s interpretation of the Fourth Amendment] where doing so will more appropriately protect the rights of this state’s citizens”); *see also Brigham City, Utah v.*

Stuart, 547 U.S. 398, 408 (2006) (noting that the Utah Supreme Court “has made clear that the Utah Constitution provides greater protection to the privacy of the home than does the Fourth Amendment”); *State v. Malloy*, 2021 UT 61, ¶ 14 n.3, 498 P.3d 358; *State v. Rigby*, 2016 UT App 42, ¶ 27, 369 P.3d 127 (citing cases).

When interpreting its own constitution, the Utah Supreme Court analyzes four primary sources: “the plain language of the text itself, the historical context when the provisions were drafted, judicial interpretation, and the particular attitudes and traditions within a state.” Samuel P. Newton, *Giving Teeth to State Constitutions: Using History to Argue Utah’s Constitution Affords Greater Protections to Criminal Defendants*, 3 UTAH J. CRIM. L. 40, 42 (2018) (citation and internal quotation marks omitted). Where, as here, the state constitutional language mirrors the federal constitution, and there is no case law directly on point, the historical context should be highly persuasive. The historical context of Article I section 14 shows that the framers of the Utah Constitution intended to adopt extra safeguards against unreasonable searches and seizures.

In 1895, a group of 107 delegates—all members of the Church of Jesus Christ of Latter-day Saints except 29—met for the Utah Constitutional Convention to draft the state constitution. *See id.* at 45. The delegates “profoundly distrusted government” and therefore sought to protect Utah citizens from abuses that occurred when authorities were permitted to conduct unlawful searches and seizures. *Id.* at 44; *see also* Tracey E. Panek, *Search & Seizure in Utah: Recounting the Antipolygamy Raids*, Utah Historical Quarterly, vol. 64, no. 4, Fall 1994, p. 1. The distrust began in the decade before the Utah Constitution was adopted, when Utahns experienced governmental intrusions into their homes as authorities relentlessly searched for individuals violating antipolygamy statutes, such as the Edmunds and Edmunds-Tucker acts. *Id. Id.* at 43.

They often entered homes illegally and without search warrants, ransacking property and searching in places where no person could reasonably hide. *Id.* at 27, 32, 43-44. Officers were often enticed by pecuniary rewards to hunt for polygamists. *Id.* at 2. And they did so by flagrantly violating the law. *Id.* at 43.

Early Utahns’ first-hand experience with intrusive searches—despite the Fourth Amendment’s protections—is a reason the framers of the Utah Constitution sought to provide additional safeguards beyond those afforded by the federal constitution. *See id.* Instead of revolting like the colonists, Utah delegates instead were inspired “to cling more firmly to the very principles [prohibiting unlawful searches and seizures that had been] overrun by corrupt officials.” *Id.*

Viewed through this historical lens, the Inspection Program violates Article I, section 14’s expansive protections by permitting local health departments to conduct overly broad searches with a financial incentive to abuse the discretion granted to them. As further explained in Section I.B.2 above, beginning on January 1, 2025, the Inspection Program authorizes local health departments to conduct warrantless raids of RTSBs. The Inspection Program is vague and overboard because it does not limit the frequency with which these raids can be conducted, nor does it limit their scope. Indeed, the Utah Supreme Court previously struck down a similarly overbroad city ordinance authorizing inspections of businesses that were licensed or applying for a license “for consumption of liquor on the premises.” *Salt Lake City v. Wheeler*, 466 P.2d 838, 838-39 (Utah 1970). There, the ordinance stated that “[t]he police department shall have access to all premises licensed or applying for license under this chapter, and shall make periodic inspections of said premises and report its findings to the board of commissioners.” *Id.* (citation omitted). Here, as in *Wheeler*, the Inspection Program permits local health departments to conduct a warrantless

search of both the private and public areas of RTSBs, and RTSBs are required to provide unfettered access to the local health departments.

As to the frequency, there is no limit on the number of times that a local health department can search a certain shop. *See generally* Utah Code § 26A-1-131(1)(b). There is also no temporal restriction preventing a local health department from returning to the same shop multiple times over a brief period of time. *See id.* Rather, the only provision bearing on the frequency of search requires local health departments to conduct “[u]nannounced follow-up examinations . . . within 30 days after any violation of Section 59-14-810.” *Id.* § 26A-1-131(1)(c). Under this regulatory scheme, overzealous health departments could target certain RTSBs and conduct numerous searches over a short span if prior searches prove fruitful. Such unbridled discretion presents a serious risk of abuse, which is especially heightened when the discretion can be used to harass historically marginalized groups, such as polygamists or, in this case, some owners of tobacco retail shops belonging to minority groups. *See Panek, supra*, p. 27 (explaining that marshals “repeatedly searched the homes” for “church leaders,” “high-profile members,” and “other elusive polygamists”).

Utah’s statute is also overbroad because it allows inspectors to search “the premises *and* all desks, safes, vaults, and other fixtures and furniture contained in or upon the premises.” Utah Code § 26A-1-131(1)(b) (emphasis added). The Inspection Program’s conjunctive “and” is significant because it expands the scope of a permissible search. Rather than limiting searches to places where contraband may be stored, the Utah Legislature has authorized inspectors to search anywhere on the premises. These overly broad searches are also akin to the antipolygamy raids where authorities searched under carpets and in drawers where no person could possibly be hiding.

See Panek, *supra*, at 3, 5 (“One of them next pulled up a piece of carpet, when Gleason asked Thompson if he thought there was anyone under there. Thompson said, ‘No,’ and Gleason exclaimed, ‘G d it, we will look any way!’”).

Finally, the Inspection Program is independently concerning because local health departments are financially incentivized to abuse their discretion in order to locate contraband. Pursuant to Section 59-14-810(8)(a), retailers who sell or offer to sell products that are not included on the registry are subject to civil penalties, including (i) \$1,000 for each product offered for sale in violation of this section” and (ii) “\$100 per day until the offending product is removed from the market or until the offending product is properly listed on the registry.” These penalties are deposited into a fund for local health departments to use for further search efforts. *See id.* § 59-14-810(12) (citing *id.* § 26A-1-131). The framers of the Utah Constitution intended to restrain government power to prohibit abusive searches of citizens’ property.

D. DHHS Violated the Administrative Rulemaking Act by Failing to Analyze the Fiscal Impact of a Proposed Rule Banning the Sale of all Unregistered E-cigarette Products.

Utah’s Administrative Rulemaking Act sets forth the mandatory procedure for DHHS to enact an administrative rule. *See* Utah Code §§ 63G-3-301 to -702. Relevant here, Subsection 63G-3-301(5) outlines the mandatory fiscal impact analysis that DHHS must perform prior to submitting the proposed rule to the Office of Administrative Rules. When assessing a rule’s fiscal impact, DHHS is directed to consider the following criteria:

- (a) the type of industries that will be impacted by the rule, and for each identified industry, an estimate of the total number of businesses within the industry, and an estimate of the number of those businesses that are small businesses;
- (b) the individual fiscal impact that would incur to a typical business for a one-year period;

- (c) the aggregated total fiscal impact that would incur to all businesses within the state for a one-year period;
- (d) the total cost that would incur to all impacted entities over a five-year period; and
- (e) the department head's comments on the analysis.

Id. § 63G-3-301(5) (emphasis added).

If that analysis causes DHHS to “reasonably expect” that a proposed rule will have “a measurable negative fiscal impact on small businesses,” DHHS must consider the several enumerated methods to reduce that impact, including,

- (a) establishing less stringent compliance or reporting requirements for small businesses;
- (b) establishing less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
- (c) consolidating or simplifying compliance or reporting requirements for small businesses;
- (d) establishing performance standards for small businesses to replace design or operational standards required in the proposed rule; and
- (e) exempting small businesses from all or any part of the requirements contained in the proposed rule.

Id. § 63G-3-301(6) (emphasis added).

Finally, DHHS’s rule analysis must be submitted with the requisite written findings:

- (8) The rule analysis shall contain:
 - (a) a summary of the rule or change;
 - (b) the purpose of the rule or reason for the change;
 - (c) the statutory authority or federal requirement for the rule;
 - (d) the anticipated cost or savings to:
 - (i) the state budget;
 - (ii) local governments;
 - (iii) small businesses; and

(iv) persons other than small businesses, businesses, or local governmental entities;

(e) the compliance cost for affected persons;

(l) the agency's analysis on the fiscal impact of the rule as required under Subsection (5);

(m) any additional comments the department head may choose to submit regarding the fiscal impact the rule may have on businesses; and

(n) if applicable, a summary of the agency's efforts to comply with the requirements of Subsection (6).

Id. § 63G-3-301(8) (emphasis added). If a proposed rule will have either a fiscal impact of more than “\$250,000 to a single person” or “\$7,500,000 to a group of persons” over a three-year period, it must be submitted to an appropriations subcommittee and interim committee before enactment.

Id. § 63G-3-301(13)(a).

DHHS shirked this mandatory process when it recently proposed substantive changes to administrative rules governing tobacco retail permits and requirements to sell e-cigarette products.

See Utah Admin. Code R384-415-4 (the “**2024 Administrative Rules**”). The 2024 Administrative Rules prohibits tobacco retailers, including UVBA members from “selling an electronic cigarette substance or an electronic cigarette product that is not included on the electronic cigarette product registry.” *Id.* R384-415-4(3); *see also id.* R384-415-7(2) (stating that it is not a violation of the administrative rules if a retailer sells an e-cigarette product that is included on the registry).

For tobacco retailers throughout the State of Utah, the 2024 Administrative Rules present a significant fiscal impact that will, collectively, far exceed \$7,500,000 over a three-year period.

See Utah Code § 63G-3-301(13)(a). The 2024 Administrative Rules will prohibit UVBA’s members from selling products that make up most of their sales revenue. DHHS did not conduct a fiscal impact of the 2024 Administrative Rules even though it was made aware through prior

litigation that similar regulations would have on UVBA’s members. (See Compl. ¶ 83-103.) In previous litigation with UVBA, DHHS had to reverse its administrative rule limiting the nicotine content of e-cigarettes to 3%. (*Id.* ¶ 88.) In that case, DHHS knew that the estimated fiscal impact for **only 16** of the State’s retailers was \$5.7 million. (*Id.* ¶ 100.) There are currently 83 RTSB members and 15 manufacturer/distributor members of the UVBA that will be impacted by the new 2024 Administrative Rules. Additionally, there are approximately 100 RTSBs who are not UVBA members that will also be impacted. UVBA members operating RTSBs report that their current inventory of flavored e-cigarettes have a retail value of \$7,943,660.19. *Bertagnolli Aff.* ¶11.

Because DHHS completely disregarded the fiscal impact that the 2024 Administrative Rules will have on RTSBs, it also failed to comply with provisions of the Utah Administrative Rulemaking Act that apply to proposed administrative rules that will “have a measurable impact on small businesses.” *See Utah Code § 63G-3-301(6).* Specifically, DHHS failed to (1) establish a less stringent and/or reasonable schedule/deadline for small businesses to comply with the 2024 Administrative Rules, (2) consider exempting small businesses from all or any part of the 2024 Administrative Rules, and (3) submit the 2024 Administrative Rules to the appropriations subcommittee and interim committee with jurisdiction over DHHS. Consequently, DHHS should be enjoined from enforcing the 2024 Administrative Rules.

II. WITHOUT A TEMPORARY RESTRAINING ORDER, PLAINTIFFS AND THEIR CUSTOMERS WILL SUFFER IRREPARABLE HARM.

Courts in the Tenth Circuit have found that irreparable harm is present where the plaintiff establishes that it would be difficult to calculate damages from harm to goodwill, diminished competitive positions in the marketplace, or loss of employees’ unique services. *Dominion Video Satellite, Inc. v. Echostar Satellite Corp.*, 356 F.3d 1256, 1263 (10th Cir. 2004); *ClearOne*

Commc'ns, Inc. v. Chiang, 608 F.Supp. 22d 1270, 1279 (D. Utah 2009); *Neways, Inc. v. Mower*, 543 F.Supp. 2d 1277, 1289 (D. Utah 2009). In *ClearOne*, for example, the court found irreparable harm where the plaintiff established in part “that its competitive market position” would be threatened without the injunction. 608 F. Supp. 2d at 1279. Irreparable harm is harm that cannot be adequately compensated in damages or for which damages cannot be compensable in money. *See Keybank Nat'l Ass'n v. Williams*, No. 20-1384, 2022 WL 402379, at *3 (10th Cir. Feb. 10, 2022). In *Hunsaker v. Kersh*, the Utah Supreme Court clarified the meaning of “irreparable harm” and stated, “Injunctive relief is not purely limited to cases where no other possible remedy will be available. Its broader purpose is preventive in nature.” 1999 UT 106, ¶ 8, 991 P.2d 67 (citation omitted).

The Tenth Circuit has acknowledged that loss of business and goodwill constitutes irreparable harm susceptible to injunction. *See Otero Sav. & Loan Ass'n v. Fed. Reserve Bank*, 665 F.2d 275, 278 (10th Cir. 1981) (reasoning that service disruption would involve consequences such as “severe confusion of processes and loss of good will and customer confidence in these institutions.” (citation omitted)); see also *Tri-State Generation & Transmission Ass'n, Inc. v. Shoshone River Power, Inc.*, 805 F.2d 351, 356 (10th Cir. 1986) (holding that “[a] threat to trade or business viability may constitute irreparable harm”); *Chem-Trol, Inc. v. Chriatensen*, No. 09-2024-EFM, 2009 WL 331625, at *5 (D. Kan. Feb. 10, 2009) (“Loss of customers, especially long-term customers in which goodwill has been developed through the years, creates irreparable harm.”). Further, “[w]hen an alleged constitutional right is involved, most courts hold that no further showing of irreparable injury is necessary.” *Planned Parenthood Ass'n of Utah v. Herbert*, 828 F.3d 1245, 1263 (10th Cir. 2016) (citations omitted). Here, Plaintiffs will unquestionably

suffer multiple forms of irreparable harm if the Electronic Cigarette Amendments are implemented and enforced beginning January 1, 2025.

First, Plaintiffs face an imminent threat that their commercial premises will be subject to unconstitutional searches and seizures to locate unregistered e-cigarette products through the Inspection Program. When assessing the “irreparable harm” alleged by Plaintiffs, the Court reasoned that “a constitutional wrong” is one that “damages cannot right.” *Id.* ¶ 148 (citing *Fish v. Kobach*, 840 F.3d 710, 752 (10th Cir. 2016) (“[T]he violation of a constitutional right must weigh heavily in [the irreparable harm] analysis.”)).

That same rationale applies here. Plaintiffs have challenged the constitutionality of the Inspection Program, arguing that it permits overly broad, unconstitutional searches and seizures which can result in criminal charges. Without injunctive relief, Plaintiffs are forced to unwittingly surrender their rights and be subject to criminal prosecution resulting from warrantless searches, while local health departments invest time and resources to conduct unlawful inspections. This is a harm that cannot be undone and should therefore be enjoined.

Second, enforcement of the Electronic Cigarette Amendments will cause imminent and irreparable harm to Plaintiffs’ business and goodwill. Threat to a party’s goodwill and business is nearly always irreparable. *See Tri-State Generation & Transmission Assoc., Inc. v. Shoshone River Power, Inc.*, 805 F.2d 351, 356 (10th Cir. 1986) (holding that “[a] threat to trade or business viability may constitute irreparable harm”); *Ticor Title Ins. Co. v. Cohen*, 173 F.3d 63, 69 (2d Cir. 1999) (noting that “it would be very difficult to calculate monetary damages that would successfully redress the loss of a relationship with a client that would produce an indeterminate amount of business in years to come”); *Flying Cross Check, LLC v. Central Hockey League, Inc.*,

153 F.Supp.2d 1253 (D. Kan. 2001) (“Loss of customers, loss of goodwill, and threats to a business’ viability can constitute irreparable harm.”) (internal quotation omitted); *GTE Corp. v. Williams*, 731 F.2d 676, 678 (10th Cir. 1984) (same).

The Electronic Cigarette Amendments will substantially decrease the number and variety of products that Plaintiffs can offer to customers. Beginning January 1, 2025, Plaintiffs may sell only e-cigarette products that have premarket authorization or pending authorization from the FDA. To date, the FDA has approved only 34 e-cigarette products. But Utah tobacco retailers will not be permitted to sell all those products, because the Utah Legislature enacted additional regulations prohibiting the sale of all flavored e-cigarette products and any products with more than 4.0% nicotine by weight or with a nicotine concentration of 40 milligrams per milliliter. Utah Code §§ 76-10-113(2); 76-10-101(16)(b). The banned products make up approximately 89 percent of Plaintiffs’ business and are the reason why customers make the effort to go to the RTSBs versus a nearby convenience store. *See Bertagnolli Aff.* ¶ 9. If Plaintiffs are unable to sell flavored e-cigarette products, they will lose most—if not all—of their existing customer base to general tobacco retailers. With the reduction in revenue and goodwill, Plaintiffs will be forced to close early next year. *See id.* ¶ 8. Despite closing, Plaintiffs will still have considerable inventory, rent and leases that remain in effect, and other overhead to pay, in addition to their employees who will be out of work.

Third, the threatened criminal penalties imposed for the sale of flavored e-cigarettes in Electronic Cigarette Amendments constitute irreparable harm. In 1908, the Supreme Court of the United States addressed the lack of a “plain and adequate remedy at law,” and thus the irreparable harm that arises from enforcement of a regulation that was alleged to be unconstitutional and

initially required that, “the proper way to test the constitutionality of the act is to disobey it, at least once, after which the company might obey the act pending subsequent proceedings to test its validity.” *Ex parte Young*, 209 U.S. 123, 163 (1908). In *Young*, the Supreme Court acknowledged that, “several years might elapse [with the business complying with the law] before there was a final determination” of the company’s legal challenge and if “the law was invalid, the property of the company would have been taken during that time without due process of law, and there would be no possibility of its recovery.” *Id.* The Supreme Court further identified that challenging the law requires a party to put themselves at risk—both civilly and criminally—requiring an RTSB to “find an agent or employee who would disobey the law, with a possible fine and imprisonment staring him in the face if the act should be held valid.” *Id.* The Supreme Court quipped, “The wonder would be that a single agent should be found ready to take the risk.” *Id.*

The 1908 *Young* precedent is not stale, but was bolstered in *Morales v. Trans World Airlines, Inc.*, wherein the Supreme Court held that when “enforcement actions are imminent—and at least when repetitive penalties attach to continuing or repeated violations and the moving party lacks the realistic option of violating the law once and raising its federal defenses—there is no adequate remedy at law.” 504 U.S. 374, 381 (1992). *Morales* thus recognizes that when a plaintiff faces the “Hobson’s choice” to either continually violate the law and “expose themselves to potentially huge liability; or violate the law once as a test case and suffer the injury of obeying the law” that party suffers irreparable harm and is entitled to injunctive relief. *Id.* at 2035–36.

Here, Plaintiffs are faced with the choice to either violate the law by selling the now contraband flavored e-cigarette products, and thus expose themselves to significant criminal

penalties, or lose their businesses. As such, Plaintiffs would suffer irreparable harm and are entitled to injunctive relief.

Finally, Utahns who rely on flavored e-cigarette products to quit smoking traditional cancer-causing tobacco products will suffer irreparable harm when their alternatives are now unavailable. Other countries that have implemented similar bans have seen a resurgence in the use of traditional smoking. The result is irreparable harm to the health and safety of Plaintiffs' customers. Emergency injunctive relief is necessary for Plaintiffs and their customers to avoid imminent, irreparable harm.

III. THE BALANCE OF EQUITIES AND PUBLIC INTEREST WEIGH IN FAVOR OF GRANTING UVBA'S REQUEST FOR INJUNCTIVE RELIEF.

When the government is the opposing party to a lawsuit, the third and fourth preliminary factors “merge.” *See NetChoice, LLC v. Reyes*, No. 2:23-CV-00911-RJS-CMR, 2024 WL 4135626, at *17 (D. Utah Sept. 10, 2024) (quoting *Aposhian v. Barr*, 958 F.3d 969, 978 (10th Cir. 2020)). As to the third factor, courts consider whether Plaintiffs’ threatened injury “outweighs whatever damage the proposed injunction may cause the opposing party.” *Resolution Trust Corp.*, 827 F.2d at 1198. The final factor then requires a finding that the injunction “would not be adverse to the public interest.” *Id.*

As a matter of law, protecting constitutional freedoms is in the public interest. *See G & V Lounge, Inc. v. Mich. Liquor Control Comm'n*, 23 F.3d 1071, 1079 (6th Cir. 1994) (“[I]t is always in the public interest to prevent the violation of a party’s constitutional rights.”) The State does not have an “interest in enforcing a law that is likely constitutionally infirm.” *Chamber of Com. of U.S. v. Edmondson*, 594 F.3d 742, 771 (10th Cir. 2010). Accordingly, when a constitutional right hangs in the balance, though, “even a temporary loss” usually trumps any harm to the defendant.

Free the Nipple-Fort Collins v. City of Fort Collins, Colorado, 916 F.3d 792, 806 (10th Cir. 2019) (quoting Wright & Miller, 11A Fed. Prac. & Proc. Civ. § 2948.2 (3d ed.)).

Because Plaintiffs have shown that it is substantially likely that the Electronic Cigarette Amendments have been preempted by federal law and violate their Fourth Amendment rights, it follows that both the balance of the equities and the public interest lean in Plaintiffs' favor. The State's interest in prohibiting use of flavored e-cigarette products does not eclipse the Fourth Amendment protections against unlawful searches and seizures. *See NetChoice*, 2024 WL 4135626, at *17 (ruling that the state's desire to protect children and adolescents from the harmful effects of social media did not outweigh the First Amendment's free speech protections); *see also Planned Parenthood Ass'n of Utah v. State*, 2024 UT 28, ¶ 223, 554 P.3d 998 (holding that the balance of the harms favored enjoining the State's enforcement of the abortion ban pending resolution of the plaintiff's constitutional challenges). The same logic applies there. Without injunctive relief, Plaintiffs will be subjected to unconstitutional warrantless inspections. The State, on the other hand, will not face any heightened risk of harm.

As explained above, the State and SLCHD are already achieving the legislative goal of reducing the rates of underage sales of e-cigarettes (at least in RTSBs) and the rates at which Utah's youth use e-cigarette products. Even under the *status quo*—which permits the sale of flavored e-cigarette products to adults 21 years or older—the number of youths who are using these products dropped to the lowest level in a decade according to recent CDC data from September 2024. The SHARP Survey revealed a similar trend in Utah.

Finally, there is a strong public interest in reducing the number of individuals who use traditional combustible cigarette products that are proven to cause cancer. As set forth hereinabove,

and previously acknowledged by DHHS when under oath, e-cigarettes represent a significant harm reduction over combustible cigarettes for users who cannot or do not want to quit consuming nicotine. While DHHS continually downplays the harm reduction potential of e-cigarettes to the public, the studies that DHHS has previously relied upon demonstrate that e-cigarettes contain 82-99% less harmful toxicants compared to combustible cigarettes. In fact, Plaintiffs respectfully submit that it is in the public's interest – and in accordance with DHHS' Strategic Plan to “Improve health outcomes, both physical and mental,” and “Build public trust in DHHS” – for DHHS to be truthful with the public about the relative risks of e-cigarettes and combustible cigarettes. This interest is apparent in the Tobacco Control Act's directives concerning the premarket tobacco application process. The Tobacco Control Act directs the FDA to review applications to determine whether “permitting such tobacco product to be marketed would be appropriate for the protection of the public health.” 21 U.S.C. § 387j(c)(2)(A). In making this determination, FDA must consider “the risks and benefits to the population as a whole.” *Id.* 387j(c)(4). This includes considering (1) the “increased or decreased likelihood that existing users of tobacco products will stop using such products” and (2) “the increased or decreased likelihood that those who do not use tobacco products will start using such products.” *Id.* § 387j(c)(4)(A)–(B).

When the FDA denied over a million applications without meaningfully considering the “risks and benefits to the *population as a whole*” it failed to consider how certain products, and especially flavored cigarette products, may decrease the likelihood of existing tobacco users to stop using those products. *See Wages & White Lion Invs.*, 90 F.4th at 380. In fact, a 2023 review of clinical trials found that “[v]aping appears to be an effective method for smoking cessation, and it is associated with a lower risk of adverse events than combustible cigarettes.” *See Ahmed M*

Ashour, *Use of Vaping as a Smoking Cessation Aid: A Review of Clinical Trials*, NATIONAL LIBRARY OF MEDICINE (July 27, 2023), <https://pmc.ncbi.nlm.nih.gov/articles/PMC10389080/>.

In Plaintiffs' experience, some of their adult customers have successfully used e-cigarette products to quit smoking. There is a risk that those customers will switch back to combustible cigarettes (and their associated increases in harm to users and others due to secondhand smoke) if e-cigarette products are only offered the same flavors as cigarettes—tobacco and menthol. Alternatively, current flavored e-cigarette users may seek products on the black market and take substantial health risks like those that gave rise to the EVALI outbreak. A recent article, published in the Guardian, aptly noted that trends in increased e-cigarette regulations may be sabotaging the public health success of declining rates of cigarette use. *See* Martha Gill, In a Moral Panic Over Vaping, We Risk Forgetting that Cigarettes Kill, The Guardian (Nov. 10, 2024 3:00 PM ET). The author explains, “It would be better if kids did not vape, but taxing vapes and restricting flavours is not the answer: this risks harming adult smokers who might otherwise be tempted to switch.” *Id.* This has already played out in Australia where there was “a rise in smoking rates” after the government “made vapes prescription-only in 2021.” *Id.*

IV. AN INJUNCTION SHOULD ISSUE WITHOUT PLAINTIFF POSTING SECURITY.

The Court should not require Plaintiff to post security as a condition of issuing the requested injunctive relief. Defendants will not incur costs, attorney fees, or damage if they are enjoined from enforcing the Electronic Cigarette Amendments. The effect of the restraining order or injunction would be for the status quo to continue. Defendants may save money that would otherwise be expended for enforcement purposes, which must be paid for out of funds received for the registry. *See* Utah Code § 59-14-807(3)(a)(vii).

CERTIFICATION OF NOTICE

Pursuant to Rule 65(a)(1), the undersigned attorneys hereby certify that copies of this Motion, supporting declarations, and the proposed order were sent to Defendants via email and certified mail. The certificate of service filed with this Motion provides further details of that service.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court grant the Motion and enter a TRO enjoining Defendants from enforcing the Electronic Cigarette Amendments. The requested relief is not only in the public interest but is necessary to preserve the *status quo* and prevent immediate irreparable harm to Plaintiffs while the case is adjudicated on the merits.

DATED: December 23rd, 2024.

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